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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,027	03/02/2004	John A. Giordano	48508-00014	9737

23767 7590 09/18/2007

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EXAMINER	
CHOI, FRANK I	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
09/18/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/790,027	GIORDANO ET AL.	
	Examiner	Art Unit	
	Frank I. Choi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 December 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *232-244* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *232-244* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 232-244 are rejected under 35 U.S.C. 103(a) as being unpatentable over Paradississ et al. (US Pat. 6,488,956) in view of Remington's Pharmaceutical Sciences and Ashmead et al. (US Pat. 4,863,898).

Paradissis et al. disclose a preferred embodiment of a multi-vitamin and mineral supplement for lactating women containing calcium in the form of a pharmaceutically acceptable calcium compound, Vitamin D, Beta-carotene, Vitamin B12, Vitamin B6, Vitamin B3, Vitamin B2, Vitamin B1, Vitamin E, about 6 to about 30 mg of elemental iron in the form of a pharmaceutically acceptable iron compound, elemental zinc in the form of a pharmaceutically acceptable zinc compound (Column 5, lines 48-68, column 6, lines 1-3). It is disclosed that the composition can also include a pharmaceutically acceptable magnesium compound and vitamin C (Column 6, lines 3-8). It is disclosed that the composition can include folic acid and about 1 mg to about 3 mg of copper (column 10, lines 40,41). It is disclosed that the invention is contemplated for use by women having vitamin or mineral deficiencies, such as niacin deficiency (Column 9, lines 18-44). It is disclosed that iron can be in the form of ferrous fumarate, magnesium in the form of magnesium oxide and zinc in the form of zinc oxide (Column 9, lines 56, 59, Column 10, line 37). It is disclosed that vitamins can be provided in

any source; for example, vitamin A can be a vitamin A precursor (Column 10, lines 55-68). It is disclosed that compositions can be prepared with pharmaceutically acceptable carriers, that the quantity of active compound in a unit dose can be varied according to the particular application and potency of the active ingredients and that the determination of proper dosage for a particular situation is well within the skill of the art (Column 11, lines 35-38, Column 12, lines 39-42).

Remington's discloses that 30 to 60 mg of supplemental iron is recommended for lactating women for 2 to 3 months in order to replenish stores of iron lost during pregnancy (Page 1004, Table I, note h). It is disclosed that an equivalent or source for vitamin D is cholecalciferol, Vitamin C is ascorbic acid, Vitamin B1 is thiamine mononitrate , Vitamin B2 is riboflavin, Vitamin B6 is pyridoxine hydrochloride, Vitamin B12 is cyanocobalamin and niacin is niacinamide (Pages 1007, 1012, 1015, 1017-1020).

Ashmead et al. disclose that copper is needed in combination with iron to build hemoglobin, is necessary for production of RNA and aids in the development of bones, brains, connective tissue and pigment formation (Column 2, lines 55-58). It is disclosed that copper is chelated by amino acids and that in this form can be absorbed by the body (Column 4, lines 9-68, Column 5, lines 1-54). It is disclosed that the amino acid chelate can be admixed with other ingredients, including excipients and vitamins (Column 7, lines 52-58).

The prior art discloses a composition containing vitamins and minerals and excipients. The difference between the prior art and the claimed invention is that the prior art does not expressly disclose a composition consisting only of the claimed vitamins, minerals and excipients. However, the prior art amply suggests the same as the prior art discloses combinations of vitamins and minerals to treat deficiencies in combination with excipients and

the use of copper chelates as sources of copper. As such, it would have been well within the skill of one of ordinary skill in the art to prepare a composition of vitamins and minerals and excipients, including the claimed composition, with the expectation that the combination would be effective in treating vitamin and mineral deficiencies as desired. Further, the prior art discloses amounts of copper and iron overlapping the claimed amounts. As such, it would have been well within the skill of one of ordinary skill in the art to vary the amount of copper and iron as desired depending on the needs of the patient, including the claimed amounts.

The Examiner has duly considered the Applicant's arguments but deems them moot in light of the new grounds of rejection herein.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 232-244 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 208-218 of copending Application No. 11/296,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because although the conflicting claims are not identical, they are not patentably distinct from each other because they both set forth compositions containing the same vitamins and minerals. Further, the '210 application claims iron in the amount of 50 mg and copper in the amount 1mg (claim 209).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

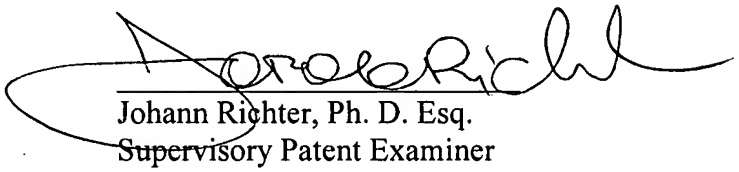
A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a flexible schedule. However, Examiner may generally be reached Monday-Friday, 8:00 am – 5:30 pm (EST), except the first Friday of the each biweek which is Examiner's normally scheduled day off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Mr. Johann Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
September 10, 2007



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